cube dx
hybCell technology

IVDR Self Certification – Class A Declaration of Conformity

European Communities Council Regulation EU 2017/746 Concerning IVD Medical Devices

IPC

Cube Dx GmbH
Westbahnstraße 55
4300 St. Valentin/Austria
SRN: AT-MF-000013909
www.cubedx.com
UID: ATU 69753849

EU Declaration of Conformity

European Communities Council Regulation EU 2017/746

Concerning IVD Medical Devices

IPC

Manufacturer: **Cube Dx GmbH**
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We hereby declare that the following mentioned products meet the provisions of the Council Regulation EU 2017/746 covering medical devices. All documentation was checked and is retained on company premises. This declaration of conformity is issued under the sole responsibility of Cube Dx GmbH. The conformity assessment has been conducted by the manufacturer under its sole responsibility, in accordance with Article 48(10) of Regulation (EU) 2017/746.

Product data:

Product Name	***UDI-DI / REF***
IPC	09120127730169

The technical documentation for listed devices is prepared according to EU 2017/746 by Cube Dx GmbH. The devices listed in the table above are in vitro diagnostic (IVD) medical devices classified as class A according to Regulation (EU) 2017/746.

Basic UDI-DI:	912012773IPCEV
Classification:	Class A, Rule 5A *Rationale: Products for general laboratory use, accessories which possess no critical characteristics (…). Product for verification of DNA extraction of low risk sample preparation kits.*
Conformity Assessment Procedure:	Conformity Assessment Route: Audit of technical documentation (EU) 2017/746 Annex II, III
GMDN Code:	66439

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EMDN Code:	W0105080808
Intended Purpose:	The IPC (Internal Process Control) is an in vitro diagnostic medical device intended for professional use only in a clinical laboratory setting as an aid to diagnosis. Its function is to serve as a qualitative internal process control to monitor the adequacy of DNA or RNA extraction. The IPC's specific DNA is introduced manually into the specimen (EDTA blood) and subsequently co-extracted. Its successful detection in follow-up analyses with Cube Dx products confirms that the extraction process worked adequately.

List of applicable standards:

Standards, directives and laws: Fundamentals	
Number	***Title***
REGULATION (EU) 2017/746	EU 2017/REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL from 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
EN ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971	Medical devices – Application of risk management to medical devices
ISO/TR 20416	Post-market surveillance for manufacturers
EN ISO 15223-1	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
EN ISO 20417	Medical devices — Information to be supplied by the manufacturer
EN 13641	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 23640	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents

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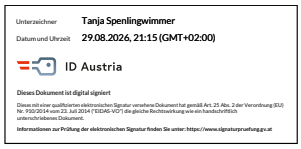
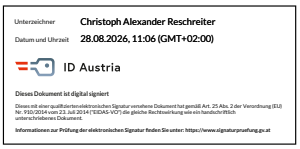
St. Valentin, 28.08.2026



Tanja Spenlingwimmer, MSc.
(PRRC, Cube Dx GmbH)



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(CSO, CubeDx GmbH)